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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

KREMER, MATTHEW J

ART UNIT PAPER NUMBER

3736

DATE MAILED: 03/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/077,196

Applicant(s)

HUIKU, MATTI

Examiner

Matthew J Kremer

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3,5,6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Objections

1. Claim 1, 10, and 12 are objected to because of the following informalities. In claim 1, line 10, "means" should follow "detector". In claim 10, " $\epsilon_{i,j}$ " in line 2 should be " $\epsilon_{i,j}$ " and " ϵ_j " in line 6 should be " ϵ_j ". In claim 12, " ϵ_j " in line 6 should be " ϵ_j ". Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-31 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites the limitation "the amount" in line 2 in which there is insufficient antecedent basis. Claim 9 recites the limitation "the temperature" in line 2 in which there is insufficient antecedent basis. Claim 10 is unclear because it includes the following symbols which are not defined: λ , $\epsilon_{ij}^{\text{effective}}$, and W . Claim 10 also recites the following limitations in which there is insufficient antecedent basis: "the emission spectrum" in line 4, "the spectral sensitivity" in line 5, and "the temperature" in line 7. Claim 24 recites the limitation "the amount" in line 1 in which there is insufficient antecedent basis. Claim 25 recites the limitation "the amount" in line 2 in which there is insufficient antecedent basis.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-9, 23-26, and 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,104,938 to Huiku et al. (cited by Applicant) in view of U.S. Patent 5,725,480 to Oosta et al. Huiku et al. discloses a method for determining the relative concentration of oxyhemoglobin, deoxyhemoglobin, and dyshemoglobin by using light absorption. (Abstract of Huiku et al.). Huiku et al. discloses the use of emitter means for emitting radiation at two different wavelengths (column 13, lines 29-48 of Huiku et al.) and detector means (column 14, lines 49-65 to Huiku et al.). The method of Huiku et al. discloses a method of calibration by carrying out initial characterization measurements, establishing nominal characteristics, and storing the reference data. (column 20, lines 7-29 of Huiku et al.). Huiku et al. does not teach determining tissue-induced changes and compensating for subjects specific variation. Oosta et al. teaches a process for determining the contribution of one or more skin parameters to the absorption and transmittance data and correcting the subsequent non-invasive measurement of a biological compound for the contribution of the skin parameters. (Abstract of Oosta et al.). Such correction procedures would result in more accurate

measurements. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the correction procedures of Oosta et al. in the method of Huiku et al. since more accurate measurements can be achieved. Oosta et al. teaches that the skin parameters can be programmed into an algorithm for measuring a biological compound. (column 6, lines 51-54 of Oosta et al.). In regard to claims 2, 4-5 and 7, the combination teaches that the skin parameter includes temperature and it is well known that temperature causes wavelength shifts. (column 6, lines 11-16 of Oosta et al.). In regard to claims 3-4 and 7, the combination teaches that the skin parameters include the water content and melanin content of a patient which is internal to the patient. (column 2, lines 32-40 of Oosta et al.). In regard to claims 5 and 7, a transformation is disclosed using the Lambert-Beer model. (column 20, lines 9-29 of Huiku et al.). In regard to claim 8, the wavelengths and spectral emission of the sensor LEDs are measured, the receiver sensitivity is considered, and the tissue characteristics are examined. (column 20, lines 9-16 of Huiku et al.). In regard to claim 9, temperature effect is examined and compensated in the measurements (column 6, lines 11-16 of Oosta et al.) and it follows that if temperature can be compensated, a baseline temperature was established as a point of reference. In regard to claims 24, the combination teaches an apparatus which includes a light source for emitting at least two wavelengths (emitter means); a receiver receiving light from the tissue and providing output signals responsive to the received light (detector means); means coupled to said receiver for processing the output signals from the receiver (first processing means); a reader means coupled to said data storage device for obtaining

extinction coefficient data (second processing means); a data storage device storing extinction coefficient data (memory means); and calculating means coupled to said processing means and said reader means for determining the amount of light absorbing substance in the blood. (claim 47 of Huiku et al.). The combination further teaches a first compensation and a second compensation algorithm (column 7, lines 18-42 of Oosta et al.) and it is well known in the art to use a microprocessor to carry out algorithms. (reference numeral 11 of Fig. 6 of Huiku et al.). In regard to claim 25, the combination teaches a sensor which includes light sources 2 for emitting at least two wavelengths (means for emitting radiation); a receiver 3 for receiving light from the tissue and providing output signals responsive to the received light (means for receiving); and a data storage device 4 for storing extinction coefficient data (storage means). (Fig. 6 of Huiku et al.). The combination further teaches how the data is used to determine tissue-induced changes. (column 7, line 18 to column 8, line 41 of Oosta et al.). In regard to claim 26, LEDs are used (column 13, lines 29-47 of Huiku et al.). In regard to claims 28-29, fiber optics can be used. (column 9, lines 7-20 of Huiku et al.).

6. Claims 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,104,938 to Huiku et al. (cited by Applicant) in view of U.S. Patent 5,725,480 to Oosta et al. as applied to claim 25, and further in view of U.S. Patent 5,348,003 to Caro. The combination does not teach the use of lasers. The combination teaches the use of LEDs. (column 13, lines 29-47 of Huiku et al.). It is well known in the art that lasers are suitable substitutes for LEDs and they are functionally equivalent. (column 9, lines 42-

50 of Caro). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute lasers for the LED to since they are functionally equivalent and Caro teaches that they are suitable substitutes.

Allowable Subject Matter

7. Claims 10-22 and 30-31 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

8. The following is a statement of reasons for the indication of allowable subject matter. The prior art does not teach or suggest that the extinction coefficients are determined by the following formula:

$$\varepsilon_{ij}^{effective} = \frac{1}{W} \int_{\Delta\lambda} \varepsilon_j(\lambda) * LED(\lambda(T)) * DET(\lambda) d\lambda.$$

The prior art does not teach or suggest storing an average transform and updating the average transform based on tissue-induced changes. The prior art does not teach or suggest the use of the Functional Light Transmission. The prior art does not teach or suggest calculating nominal values for function F_{kl} which corresponds to the

$$\text{ratio: } \frac{f_a(\mu_a^k - \mu_v^k) + \mu_v^k}{f_a(\mu_a^l - \mu_v^l) + \mu_v^l}.$$

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J Kremer whose telephone number is 703-605-


0421. The examiner can normally be reached on Mon. through Fri. between 7:30 a.m. - 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eric Winakur can be reached on 703-308-3940. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0758 for regular communications and 703-308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



Matthew Kremer
Assistant Examiner
Art Unit 3736
March 20, 2003



ERIC F. WINAKUR
PRIMARY EXAMINER